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EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: Line 2 contains the undefined acronym "EMG". It is suggested to replace "EMG" in line 2 with --electromyogram--. Line 9 contains the undefined acronym "EKG". It is suggested to replace "EKG" in line 9 with --electrocardiogram--. In line 12 it is suggested to replace "estimate" with --estimated--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 41-45, 47-50, 53, and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Lines 9-12 of claim 41 recite "automatically electronically estimating a contribution of an EKG signal of the subject to said raw signal and a contribution of EMG signal of the subject to said raw signal, to obtain an estimated EKG signal and an estimate EMG signal". The specification does not appear to describe how to automatically electronically estimate a contribution of an EKG signal

Art Unit: 3736

of the subject to the raw signal or how to automatically electronically estimate a contribution of an EMG signal of the subject to the raw signal such that one of ordinary skill in the art could accomplish these steps.

4. Claims 41-45, 47-50, 53, and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Lines 9-12 of claim 41 recite “automatically electronically estimating a contribution of an EKG signal of the subject to said raw signal and a contribution of EMG signal of the subject to said raw signal, to obtain an estimated EKG signal and an estimate EMG signal”. The specification does not appear to disclose automatically electronically estimating a contribution of an EKG signal of the subject to the raw signal or automatically electronically estimating a contribution of an EMG signal of the subject to the raw signal. Lines 15-16 recite “filtering said EMG signal out of said raw signal only within said frequency range of said window”. The specification does not appear to disclose “filtering said EMG signal out of said raw signal only within said frequency range of said window”.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3736

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 41, 42, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,524,623 to Stein et al. (“Stein”).

Please note that because it is unclear from the specification what is meant by “automatically electronically estimating...” the following rejection has been made according to the Examiner’s best interpretation of the claimed invention.

In reference to Claim 41

Stein teaches a method (see Fig. 4) for determining an EMG signal out of a raw signal comprising the steps of: obtaining a plurality of signals from a subject via a plurality of electrodes (160, 162) configured to interact with the subject to detect signals from the diaphragm of the subject, each electrode having a signal channel associated therewith (col. 6 lines 30-45, each electrode is a channel); combining the respective signals of the signal channels to form a multi-channel raw signal (col. 6 lines 35-40); automatically electronically estimating a contribution of an EKG signal of the subject to said raw signal (the ECG signal is automatically electrically input into circuit 154 and serves as an estimate of the contribution of an EKG signal picked up by electrodes 160,162 to the raw signal, because the signals determined by the separate ECG electrodes and EMG electrodes would be at least slightly different due to differing locations) and a contribution of EMG signal of the subject to said raw signal (see Fig. 4, bandpass filter effectively serves this function due to its boundary frequencies), to obtain an estimated EKG signal and an estimated EMG signal; and dependent on said

Art Unit: 3736

estimated EKG signal and said estimated EMG signal, automatically electronically determining an EMG window in a frequency range (the portion of the raw signal which is removed and replaced could fairly be considered an EMG window, as it is replaced with EMG data; this window would inherently be in some frequency range, for example, the frequency with which the ECG signals appear) and filtering said EMG signal out of said raw signal (the signal passing from 408 is the EMG signal, and has been filtered out of the original raw signal) only within said frequency range of said window (the filtering occurs with the frequency of the ECG signal).

In reference to Claim 42

The method of claim 41 comprising filtering said EMG signal that is filtered out from said window (via LOW PASS).

In reference to Claim 44

The method of claim 41 comprising automatically electronically determining a width of said window dependent on said estimated EKG signal and said estimated EMG signal (in order to replace a section, its length must somehow be determined).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3736

8. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein in view of US Pat. No. 5,671,752 to Sinderby et al. ("Sinderby").

In reference to Claims 48-50

Stein teaches the method of claim 41 but does not teach determining a middle frequency of the estimated EMG and using the middle frequency to monitor/measure at least muscle fatigue and muscle activity of the patient, activating a humanly perceptible alarm dependent on deviation of said monitored or measured muscle fatigue from a reference value, or automatically controlling a ventilator configured to interact with the patient to provide ventilation support to the patient dependent on said monitored or measured muscle fatigue. Sinderby teaches a method in which the center frequency of a diaphragmatic EMG signal is used to measure muscle activity fatigue and to optimize ventilator support (col. 10 lines 1-20). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Stein by using the central frequency of the diaphragmatic EMG signal to measure muscle fatigue in order to automatically optimize ventilator support as taught by Sinderby because this substitution would predictably result in controlling a ventilator using a diaphragmatic EMG signal as taught by Sinderby. Additionally, by controlling the ventilator based on the diaphragmatic fatigue, a humanly perceptible signal would be produced in the form of the motion/sound of the ventilator in response to a deviation of the fatigue from a reference value.

***Response to Arguments***

9. Applicant's arguments with respect to claims 41-45, 47-50, and 80 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.



Art Unit: 3736

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 1/8/09

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736